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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,239	07/17/2003	Anthony L. Fitzhugh	14364.99	8121

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MEDTRONIC VASCULAR, INC.
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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,239

Applicant(s)

FITZHUGH ET AL.

Examiner

Blessing M. Fubara

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 32-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/4/03 & 5/24/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 09/04/03 and 05/24/03; change of power of attorney filed 09/02/04 and preliminary amendment filed 07/13/03 and 11/01/04.

Priority

Examiner acknowledges this application as a divisional of application 09/972,219, which is now US 6,703,046.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-26 and 33-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of highly cross-linked and extremely hydrophobic is vague and indefinite. What is highly cross-linked or how much cross-linked is highly cross-linked? What is extremely hydrophobic and how hydrophobic is the polyamine?

Claim 33 does not recite method steps and thus no active steps are present in treatment method.

It is not clear in claim 34 how the blood coagulation is prevented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Pulfer et al. (Incorporation of Nitric Oxide-Releasing Crosslinked polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997; pp 182-189).

Pulfer discloses cross-linked polyethyleneimine microspheres that are derivatized with Nonates and the NO-releasing microspheres are incorporated into the pores of the vascular graft (right column of page 187).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3, 4, 7, 8, 14-22, and 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pulfer et al. (Incorporation of Nitric Oxide-Releasing Cross-linked polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997; pp 182-189).

Pulfer discloses the cross-linked nitric oxide releasing polyamine-functionalized polymer of the instant claim. Pulfer does not specifically disclose treating infections. The vascular graft of Pulfer is porous and there is no demonstration in applicants' specification indicating that the recited pores size ranges provides unusual results. However, Pulfer discloses method of

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delivering NO to blood vessels with the polymeric NO-donor and since the NO is delivered to blood, it would inherently treat infection because the NO goes into the blood circulation. And claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the vascular graft containing the NO-releasing cross-linked microsphere to the blood vessel as disclosed by Pulfer. One having ordinary skill in the art would expect the NO released to the blood circulation to perform the function inherent to the NO.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Trescony et al. (US 5,994,444) discloses a biodegradable polymeric matrix that has nitric oxide donor dispersed throughout at least a portion of the polymeric material (abstract, column 3, lines 6-11, column 5, lines 34-51). Trescony differs from the instant claims in that in the prior art, the nitric oxide donor is dispersed in the matrix whereas in the instant application the nitric oxide donor is part of the polymer.

Keefer et al. (US 5,676,963) discloses implants, stents and prosthesis that comprise a polymeric composition having a nitric oxide releasing $N_2O_2^-$ functional group bound to the polymer (abstract). The polymer of the prior art is not a polyamine derivatized polydivinylbenzene.

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8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

